Ser. No. 10/519,897 Docket No. 100758-1P US (133087.07001)

#### REMARKS

Claims 1-36 were pending. Claims 1-19, 26-30 and 35-36 have been amended, support for which can be found, for example, in the original claims. Claims 4-15 and 26-30 (and claims 3, 35, and 36) have been amended to remove the multiple dependency upon another multiply dependent claim. Claims 20-25 and 31-34 are canceled without prejudice to their presentation in another application. For proper dependency purposes, new claims 37-40 have been added, support for which can be found, for example, at the originally filed claims 26-27 and 35-36. New claims 41-44 have been added, support for which can be found, for example, at page 37, lines 27-32 and page 38, lines 1-2 of the specification. No new matter has been added. Upon entry of the present amendments, claims 1-19, 26-30 and 35-44 will be pendine.

## Claim rejections under 35 U.S.C. §112

- 1. Claims 20-21 are rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite and for allegedly failing to particularly point out and distinctly claim the subject matter which the applicants regard as their invention. In view of the cancellation of claims 20-21, this rejection becomes moot. Applicants, however, respectfully point out that claims 20-21 are "medical use claims" under common European Patent practice, thus the cancellation thereof will not affect (or narrow) the scope of other claims such as the pharmaceutical composition claim (claim 19) or method of treatment claims (e.g., claims 26-27).
- 2. Claim 18 is rejected under 35 U.S.C. §112, first paragraph and second paragraph, for allegedly failing to describe or to describe in such full, clear and exact terms as to enable one skilled in the art to make and use the same; and or and for allegedly failing to particularly point out and distinctly claim the subject matter which the applicants regards as their invention. More specifically, the Office alleges that Step i) at the end of claim is unclear and not enabling. Although Applicants believe that one of ordinary skill in the art would understand and be enabled to make and use the claimed invention, from the disclosure of the present application coupled with the common knowledge of the art (for example, if desired and necessary, a hydroxyl group can be converted into an ester group by reacting with an appropriate acid), in an earnest effort to pursue allowance, Applicants have deleted the original Step i). In view of the deletion, this rejection becomes moot.

19

Ser. No. 10/519,897 Docket No. 100758-1P US (133087.07001)

- 3. Claim 1-15, 18-36 are rejected under 35 U.S.C. §112, first paragraph and second paragraph, for allegedly failing to describe in such full, clear and exact terms as to enable one skilled in the art to make and use the same; and/or for allegedly failing to particularly point out and distinctly claim the subject matter which the applicants regards as their invention. More specifically, the Office pointed to the usage of "the ...ammonio substitutent" in R<sup>23</sup> (and possibly elsewhere). Applicants have amended claim 1 (by deleting "N.N.N-(C<sub>1-10</sub>alkyl)<sub>3</sub>ammonio" in the variables such as R<sup>14</sup>, R<sup>23</sup>, R<sup>25</sup>, R<sup>27</sup>, R<sup>33</sup>, R<sup>38</sup>, R<sup>44</sup>, R<sup>48</sup> and R<sup>44</sup>). In view of the current amendment, this rejection becomes moot. However, one of ordinary skill would appreciate that an amine compound of the present invention [having an N.N-(C<sub>1-10</sub>alkyl)<sub>2</sub>amino group] can be readily converted to a quaternary ammonium salt [having an N.N.N-(C<sub>1-10</sub>alkyl)<sub>3</sub>ammonio and a counter ion such as CT], in view of the disclosure of the present specification coupled with the common knowledge of the art. Applicants respectfully point out that the deletion of "N.N.N-(C<sub>1-10</sub>alkyl)<sub>3</sub>ammonio" in the claims will not affect the scope of the claims under the doctrine of equivalents.
- 4. Claim 1-36 are rejected under 35 U.S.C. §112, first paragraph and second paragraph, for allegedly failing to provide enablement for solvates. Although Applicants disagree, solely to advance prosecution, the claims have been amended to delete "solvate." In view of the present amendment (deletion of "solvate, solvate of such a salt" from all pending claims), this rejection also becomes moot.
- 5. Claims 22-26 (sic) and 31-34 are rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite and for allegedly failing to particularly point out and distinctly claim the subject matter which the applicants regards as their invention. More specifically, the Office pointed out that these use claims (equivalent to method claims) do not set forth any positive steps. Applicants respectfully submit that claim 26 is a proper method claim that recites an administration step. In view of the cancellation of claims 22-25 and 31-34, this rejection becomes moot. Applicants also point out cancellation of claims 22-25 and 31-34 will not affect (or narrow) the scope of other claims such as the method of treatment claims (e.g., claims 33-36).

# II. Claim rejections under 35 U.S.C. §101

Claims 22-26 (sic) and 31-34 are rejected under 35 U.S.C. §101 as allegedly failing to set forth any steps involved in the process (resulting in an improper definition of a

process). Applicants respectfully submit that claim 26 is a proper method claim that recites an administration step. In view of the cancellation of claims 22-25 and 31-34, this rejection becomes most

## III. Claim Objections

Claims 4-15 and 19-34 are objected to under 37 CFR 1.75(c) as being in improper form (a multiple dependent claim cannot depend on another multiple dependent claim). In view of the current amendment, this objection becomes moot (for example, claim 3 is amended to depend from claim 1 only; for another example, claims 4-15 are dependent only on claims 1-3).

#### IV. Conclusion

In view of the foregoing, Applicants respectfully request reconsideration of the rejections/objections in light of the above comments and amendments. Early allowance of all pending claims is respectfully requested.

The Commissioner is hereby authorized to debit any fee due or credit any overpayment to deposit account 50-0436.

Respectfully submitted,

/Feng Shao, Reg.# 54733/ Feng Shao

Date: July 30, 2007

### PEPPER HAMILTON LLP

3000 Two Logan Square Eighteenth and Arch Streets Philadelphia, PA 19103-2799 (215) 981-4142 (Telephone) (215) 754-4625 (Facsimile)